IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler
This relates to: All Actions	**Plaintiffs' Reply Memorandum of Law in Further Support of Plaintiffs' Motion to Exclude the Expert Testimony of Lauren Stiroh, Ph.D.**

PLAINTIFFS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF LAUREN STIROH, PH.D.

On the Brief:

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I. INTRODUCTION

Defendants' response (ECF 2079) confirms that Dr. Stiroh erroneously conflates two notions of "value" in her expert declaration: the "value" consumers (or TPPs) might *theoretically* ascribe to adulterated VCDs that they *may* want to purchase even if they 'knew the truth' of the adulteration (*see, e.g.*, Defs.' Mot. at 7) (arguing Dr. Stiroh opines that some "patients [may] choose to purchase or consume medications that are not FDA-approved"), and the "therapeutic value" class members may have received from the VCDs they actually purchased and for which they seek economic loss damages in this litigation (*id.* at 6), which Defendants and Dr. Stiroh contend results in the VCDs purchased by the EL Plaintiffs having some non-zero value (*id.*).

The former is an unreliable opinion that must be excluded because it presumes, in a counterfactual but-for world, that class members could have purchased adulterated or contaminated VCDs had the truth of the nitrosamine contamination been known at the time of purchase. This is because, by law and Downstream Defendants' own admissions, adulterated drugs cannot be and are not sold in the United States. Thus, no class member could have bought an adulterated VCD if the nitrosamine contamination were disclosed earlier, even if they wanted to do so. Dr. Stiroh's opinions to the contrary are unreliable and unhelpful because they do not square with the undisputed facts (and commercial realities) of this litigation.

Dr. Stiroh's latter opinion, about potential therapeutic value class members received for VCDs they actually purchased overlooks the fact that Dr. Conti's analysis *does* consider the therapeutic value the drugs have to the consumers. More fundamentally, Dr. Stiroh's opinion that the point-of-sale cost should be diminished in value likewise is unreliable and does not fit the facts of this case.

The entire legal system is rooted in the fact that for a plaintiff to receive damages, the plaintiff's losses must flow from the defendant's wrongdoing. Here, the wrong to class members occurred at the point-of-sale, when the economic loss Plaintiffs purchased VCDs they believed where therapeutically equivalent to the RLD. The products purchased by class members were not what they believed them to be – and instead were adulterated with nitrosamines, a known human carcinogen. While Dr. Stiroh attempts to muddy the water arguing that there should be diminutions of the amounts paid, these factors are irrelevant, as they are completely untethered from the actual claims in this case, and the actual injury suffered by Plaintiffs.

For these reasons, Dr. Stiroh's opinions should be excluded.

II. ARGUMENT

A. Dr. Stiroh's Opinions that Class Members Would Have Been Able to Choose to Buy Adulterated VCDs Remains Unreliable, Unreliably Applied and Unhelpful

Plaintiffs explained in their opening motion why the Court should exclude Dr. Stiroh's opinions that class members might have still purchased and paid for VCDs even if the truth of adulteration and nitrosamine contamination were disclosed earlier. Dr. Stiroh's model ignored the reality that **none** of the EL Class Plaintiffs could have purchased VCDs had the truth been known earlier, because in that situation the VCDs would have been removed from the market, as they were in the real world, only sooner. *See* Pls.' Mot. at 4-6 (explaining how federal and state law bans sale of adulterated drugs, and how Downstream Defendants testified they do not and cannot sell adulterated drugs); *see also* Defs.' Mot. at 7 (claiming "Dr. Stiroh explains that patients choose to purchase or consume medications that are not-FDA-approved," i.e., adulterated).

Defendants do not tackle this head on. Rather, they conflate this fatal flaw in her methodology with the *different* concept of therapeutic value, which is an (equally flawed) argument: the value of the contaminated VCDs that were dispensed in the real world (and not what class members might choose to do or pay in a counterfactual but-for world where the truth was known earlier and adulterated drugs could legally be sold). *See* Defs.' Mot. at 1. Indeed, Defendants appear to concede that Dr. Stiroh

does not opine on what any class members might have done if the adulteration and nitrosamine contamination were disclosed earlier. Defs.' Mot. at 7 (arguing her opinions "do not depend on any assumptions as to whether those individuals would have been able to purchase VCDs if they had been deemed adulterated."); *see also id.* at 7-8 (arguing Dr. Stiroh only opines about the "received value from consuming VCDs").

Given this, Dr. Stiroh's opinions must be excluded to the extent she opines that class members may have chosen to purchase VCDs even if they were found to be adulterated or contaminated earlier.

B. Dr. Stiroh's Opinions About the Value of "Consumed" VCDs and "Diminution of Value" of Adulterated VCDs Remains Unreliable and Irrelevant

None of Defendants' retorts about Dr. Stiroh's opinions on the value of consumed VCDs – that Dr. Conti purportedly ignores therapeutic value, that adulteration diminishes value of VCDs to some non-zero amount, and that alternative medication existed (Defs.' Mot. at 5-15) – overcome the core flaws rendering these opinions unreliable and unhelpful.

1. Dr. Stiroh Is Wrong That Dr. Conti's Analysis Did Not Consider Therapeutic Value

Dr. Stiroh's opinions are inherently unreliable because she purposefully misconstrues the full contours of Dr. Conti's report. Critically, Dr. Stiroh writes that Dr. Conti "wholly fails to consider how therapeutic value factors into the overall

economic value of the VCDs." Pls.' Mot., Ex. 1 (Stiroh Rpt.) at ¶ 28. Dr. Stiroh further elaborates that "[a] meaningful economic analysis must account for the benefits of a product, and Dr. Conti's opinion on economic value is incomplete without consideration of therapeutic value." *Id.*

However, the actual full expert discovery record makes clear that Dr. Conti did consider and/or account for therapeutic value and ascribes the therapeutic value as part of the demand curve. *See* Ex. A hereto, Conti Dep. Tr. Vol. I 156:224 ("Q: You don't dispute that consumers who took valsartan at-issue products may have experienced therapeutic benefits? A: Again, the demand curve for these products may exist. From an economic theory perspective, the demand curve represents individual assessments of benefits and costs of prescription drugs. I am not disputing that there may have been a demand curve for these products."); *Id.* at 164:2-10 ("Q: Your methodology does not take into consideration how consumers might have perceived the value of the at-issue valsartan to them, correct? A: My analysis presumes there is a demand curve for these products. What my analysis also presumes is that there is no legitimate supply curve for products that do not meet the [standard necessary to sell drugs in the United States].")

Dr. Stiroh's opinions regarding Dr. Conti's analysis of "therapeutic value" should be excluded because there is no probative value in arguing that "consumers might have had low blood pressure when taking Valsartan" (which the fact-finder

itself is equally poised to understand). *See Macaluso v. Herman Miller, Inc.*, 2005 WL 563169, at *1 (S.D.N.Y. Mar. 10, 2005) (concluding that an expert's testimony must be excluded under Daubert "because it is based on incorrect factual assumptions that render all of his subsequent conclusions purely speculative" because it contradicted testimony).

2. Dr. Stiroh's Singular Focus on Therapeutic Value Ignores Supply-Side Realities and is Therefore Unreliable

Moreover, Dr. Stiroh's opinions regarding the "therapeutic value" being the overriding determinate of the value of the product is flawed for completely ignoring any "supply side" factors. Indeed, as was held in a case involving the sale of pharmaceutical product Cymbalta, when an expert looks "only to consumer demand while ignoring supply," this is similarly unreliable because the court found absolutely no support for the proposition that a "consumer may recover based on consumers' willingness to pay irrespective of what would happen in a functioning market (i.e. what could be called sellers' willingness to sell)." *Saavedra v. Eli Lilly & Co.*, 2014 WL 7338930 (C.D. Cal. Dec. 18, 2014). *See also In re Volkswagen "Clean Diesel" Mktg., Sales Practices, & Prods. Liab. Litig.*, 500 F. Supp. 3d 940 (N.D. Cal. 2020) (excluding conjoint analysis in part because it ignored supply-chain factors in creating the supply and demand curve).

3. Dr. Stiroh's Opinions on Diminution of Value Lack Reliability or Fit

Dr. Stiroh's criticisms of Dr. Conti's point of sale analysis are likewise completely untethered to the claims at issue in this case. It has been well established for over 100 years that in any lawsuit for damages, loss must flow out of the wrong and be its natural and proximate consequence. *Smith v. Bolles*, 132 U.S. 125, 130 (1889); *see also Comcast Corp. v. Behrend*, 569 U.S. 27, 34-36 (2013).

Here, the wrong occurred at the point of sale – Defendants warranted they were selling valsartan manufactured in a cGMP compliant way that was safe, effective, free from undisclosed contaminants, and the same as the reference listed drug. The product purchased by class members was not. As such, the damages which flowed from that transaction at the point of sale are what matters, and any of the other hypothetical drugs, payments or costs are totally irrelevant to this – a case which seeks damages for the breach of warranty or duty which occurred at the point of sale.

4. Dr. Stiroh's Views on "Alternative Medications" Do Not Salvage Her Unreliable Opinions

Dr. Stiroh's views on a hypothetical "alternative world" (Defs. Br. at 2) in which class members may have purchased alternative medications does not save her infirmed opinions. This is merely a re-characterization of the same faulty opinions

on what a counterfactual but-for world may have looked like,[1] and are tantamount to an argument for the jury about whether the Class's damages should be reduced by any offsets or adjustments. This is not grounded in any admissible facts and is not germane to class certification at all, as thoroughly addressed in Plaintiffs' class certification briefing. *See* Pls.' Consumer EL Br. (ECF 1748) at 67-69; Pls.' Consumer EL Reply (ECF 2057) at 12, 18.

Dr. Stiroh tries to2022 fit a square peg in a round hole. She attempts to apply an economic practice routinely utilized in antitrust cases to this, a case essentially predicated on duty, warranty, and representations.[2] By contrast, in antitrust cases, economists sometimes model actual experience in the real world with what the plaintiffs' experience would have been in a 'but for' world absent the antitrust violation. *See In re Rail Freight Fuel Surcharge Antitrust Litig.*, 292 F. Supp. 3d 14, 56 (D.D.C. 2017). However, here, because the harm occurred at the moment the

[1] Defendants are incorrect that Plaintiffs did not challenge this aspect of Dr. Stiroh's opinions. *See* Defs.' Br. at 2. These opinions of the "alternative world" were part of Dr. Stiroh's overarching opinions regarding what might have happened in this hypothetical counter-factual world where Plaintiffs both knew the VCDs had nitrosamines in them and were able to still purchase them. In this counterfactual world Dr. Stiroh also argues that even accepting the possibility that the drugs were not on the market because they had been recalled, the Plaintiffs would have spent the same or more than they did for alternatives or other non-contaminated VCDs. As Plaintiffs discuss herein, this opinion is unreliable, completely untethered to Plaintiffs' state-law claims, and consequently do not fit the facts of this case.

[2] Taken to its logical end, if "the cost of alternative products" were a viable defense in consumer warranty or similar cases, there would be no viable case (individual or class), because Defendants would be able to claim that the Plaintiffs would have purchased something else. The reason courts do not even entertain these types of irrelevant arguments is because damages are losses attributable to a wrong, and what Plaintiffs might have done in a completely counterfactual world has no bearing on the loss that was traceable to the breach of warranty or other wrongful conduct.

Plaintiffs purchased the product, such modeling is not only irrelevant, but also it does not fit the facts of the case.

Even accepting, *arguendo*, this academic hypothetical exercise of trying to predict what would have occurred in the absence of the alleged wrongdoing, it is obvious that absent Defendants' wrongdoing, the result would have been that Plaintiffs would have purchased what they were expecting to receive – a drug free of nitrosamine impurity or adulteration. *That* is the proper "but-for world." As such, Dr. Stiroh's analysis regarding the overarching market conditions and what might have happened are manifestly irrelevant and have no tangible connection to this litigation. This warrants exclusion.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Exclude the Testimony of Dr. Lauren Stiroh should be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of June, 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ David J. Stanoch
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